Exhibit F

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ORIGINAL

THE CITY OF NEW YORK,

Plaintiff,

JUDGE JONES

v.

ABBOTT LABORATORIES, INC., ALCON LABORATORIES, INC., ALLERGAN, INC., ALPHARMA, INC, AMGEN, INC., ANDRX CORP., ASTRAZENECA PHARMACEUTICALS LP, AVENTIS PHARMACEUTICALS INC., BARR LABORATORIES, INC., BAYER CORP., BEN VENUE LABORATORIES, INC., BIOVAIL PHARMACEUTICALS, INC., BOEHRINGER INGELHEIM CORP., BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., BRISTOL-MYERS SQUIBB COMPANY, DERMIK LABORATORIES, INC., DEY INC., EISAI, INC., ELI LILLY AND COMPANY, ENDO PHARMACEUTICALS, INC., ETHEX CORP., FOREST LABORATORIES, INC., FOREST PHARMACEUTICALS, INC., FUJISAWA HEALTHCARE, INC., FUJISAWA USA, INC., GENZYME CORP., GILEAD SCIENCES, INC., GLAXOSMITHKLINE PLC, HOFFMAN-LA ROCHE, INC., IMMUNEX CORP., IVAX CORP., IVAX PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA PRODUCTS, LP, JOHNSON & JOHNSON, MCNEIL-PPC, INC., KING PHARMACEUTICALS, INC., MEDIMMUNE, INC., MERCK & CO., INC., MONARCH PHARMACEUTICALS, INC., MYLAN LABORATORIES, INC., MYLAN PHARMACEUTICALS, INC., NOVARTIS PHARMACEUTICALS CORP., NOVO NORDISK PHARMACEUTICALS, INC., ONCOLOGY THERAPEUTICS NETWORK CORP., ORGANON USA, ORTHO BIOTECH PRODUCTS LP, ORTHO-MCNEIL PHARMACEUTICAL, INC., PAR PHARMACEUTICAL, INC., PURDUE PHARAMA, L.P., PUREPAC PHARMACEUTICAL CO., RELIANT PHARMACEUTICALS, ROCHE LABS, ROXANE LABORATORIES, INC., SANDOZ, INC., SANOFI-SYNTHELABO, INC., SCHERING-PLOUGH CORP., SERONO, INC., SMITHKLINEBEECHAM CORP. d/b/a GLAXOSMITHKLINE, TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAP PHARMACEUTICAL PRODUCTS, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., UDL LABORATORIES, INC., WARRICK PHARMACEUTICALS CORP., WATSON PHARMACEUTICALS, INC., WATSON PHARMA, INC., and WYETH.

Defendants.

INDEX No.

CV 06054

JURY TRIAL REQUESTED

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COMPLAINT

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The City of New York ("the City"), by its attorneys, KIRBY, McINERNEY & SQUIRE, LLP and MICHAEL A. CARDOZO, Corporation Counsel of the City of New York, for its complaint against the above-named defendants, alleges, on information and belief, as follows:

I. INTRODUCTION

1. The City brings this action against the defendant manufacturers of prescription drugs to recover monetary damages, and for civil penalties, declaratory and injunctive relief, restitution, disgorgement of profits, and treble and punitive damages suffered by it and by the State and federal governments from 1992 to the present as a result of defendants' fraudulent and misleading schemes to overcharge the Medicaid program.

2. The City pays approximately 25 percent of Medicaid costs of City residents. N.Y. Soc. Serv. L. §§ 367-a and 368-a; 42 U.S.C. §1396d(b). The State pays another 25 percent, and the federal government pays 50 percent. The City's share of Medicaid prescription drug costs for City residents was $597,544,188 in 2003.

3. There are two components of the price Medicaid pays for prescription drugs. One is determined by the Average Wholesale Price ("AWP"); the other is determined by the Best Price (defined by federal statute as the lowest price paid to any purchaser) and/or Average Manufacturer's Price ("AMP"). Defendants' fraudulent schemes involve both components. Their fraudulent inflation of AWPs and Best Prices and their failures to pay proper rebates has resulted in overcharges of many millions of dollars to the City's Medicaid program.

4. The first component is the price initially paid by Medicaid to the provider – generally a dispensing pharmacy – of the drug. This price is determined by New York State law, based on price information provided by the manufacturers. State law provides

that Medicaid will reimburse the provider pursuant to a formula based on AWP. N.Y. Soc. Serv. L. §367-a(9). AWP is not only used by Medicaid. It is also the basis for reimbursement by private insurers and self-insured employers (both also known as "third-party payors"). AWPs for each dosage and packaging of each drug are published by several industry publishing services based wholly on information supplied by the drugs' manufacturers. Thus, although the Medicaid program pays based on AWP, the setting of AWP is in the control of the manufacturers.

5. Defendants provide grossly inflated pricing information to the publishing services, causing them in turn to publish similarly inflated AWPs. Their purpose in doing so is to create a large spread between the actual price that providers such as pharmacists pay to acquire drugs and the reimbursement that those same entities receive from Medicaid, Medicare and private third party payors. Defendants advertise this spread as a reason why those in the distribution chain should sell their drugs, a practice is known as "marketing the spread." The spread is an incentive, in effect a bribe, to the pharmacists who distribute drugs and to intermediaries such as pharmacy benefits managers ("PBMs") that administer health plans to induce them to increase demand for defendants' drugs and to select defendants' drugs over competing drugs.

6. Indeed, defendants compete in the fraudulent reporting in an effort to create the greatest spread, and thereby to encourage pharmacies and doctors to prescribe or distribute their drugs, and to encourage PBMs to include their drugs in formularies. Through defendants' manipulation of AWP, they induce the Medicaid program, as well as Medicare and private payors, to pay this unlawful incentive to the purchase of defendants' products.

7. These practices have been uncovered by government investigations, by litigation, and by the press. The Wall Street Journal described one set of contracts involved in the sale of the antidepressant and antiobsessional drug Fluoxetine, manufactured by Defendant Par Pharmaceutical, Inc. of New Jersey. *See Rx for Margins: Hired to Cut Costs, Firms Find Profits In Generic Drugs, Pharmacy-Benefit Managers Can Take Huge Markups And Still Offer 'Discounts,' Making $170 On Just 90 Pills*, WSJ., March 31, 2003, at A1. The AWP for Fluoxetine is $2.66 per pill. The pharmacist can purchase Fluoxetine for approximately 5 cents per pill. According to the Wall Street Journal, the health plan paid AWP minus 73%, or 60 cents per pill, to a PBM, Express Scripts, which in turn contracted with dispensing pharmacists approved by it to pay them 25 cents per pill, or AWP minus 94%. The PBM's profit was 35 cents per pill, and the pharmacist's profit was 20 cents per pill. Both pharmacists and PBMs frequently play roles in deciding which drug a patient ultimately receives, the PBM by including or not including the drug on a formulary of drugs that each health plan will pay for, and the pharmacist by selecting among competing generic drugs in cases where such competition exists. Often, the PBM will also act as a mail order pharmacy, and can then collect both the PBM's profit and the pharmacist's.

8. In 2002 alone, the City spent over $633,000 on Fluoxetine. The City was overcharged at least 40% on each pill as a result of Par's false AWPs. *See* Exhibit B.

9. The second component of the Medicaid price is a federally mandated rebate that drug manufacturers pay to the states, and is calculated by the United States Department of Health and Human Services based on price information provided quarterly by the manufacturers. 42 U.S.C. § 1396r-8 (the "Medicaid rebate statute"). The rebate is based on two statutorily defined prices, the Best Price and the AMP. Best Price is the

lowest price paid by any purchaser, while AMP is the average price paid to the manufacturer by wholesalers. *See* 42 U.S.C. § 1396r-8(c)(1)(C) (defining Best Price); 42 U.S.C. § 1396r-8(k)(1) (defining AMP).

10. As in their setting of AWPs, defendants fail to properly calculate their Best Price, AMP or amount of rebate owed. Defendants omit in their rebate calculations routine discounts, such as volume discounts, the customary two-percent prompt pay discount, chargebacks, rebates, free samples and other off-invoice transactions and inducements or "soft discounts" offered to create market share and demand for their products.

11. A 2001 report issued by the Department of Health and Human Services ("HHS") found that many manufacturers had excluded from their Best Price calculations the discounted prices paid by HMOs, which were as much as 75 percent below the reported Best Price. *See Medicaid Drug Rebates – Sales to Repackagers Excluded From Best Price Determinations*, HHS Office of the Inspector General (Mar. 27, 2001).

12. In 2003, two defendants herein, Bayer and GlaxoSmithKline, agreed to pay $346 million to resolve allegations that they defrauded Medicaid and Medicare by engaging in a scheme known as "lick and stick," wherein they relabeled their products before selling them to Kaiser Permanente Medical Care Program (the nation's largest HMO) at deep discounts, in order to exclude these discount-priced sales in computing and reporting their Best Prices.

13. Numerous federal criminal and civil prosecutions and investigations illustrate that fraud with respect to both components of Medicaid pricing is pervasive among defendants. Defendant Abbott is paying $621 million in criminal and civil penalties for defrauding Medicare and Medicaid and has affirmatively acknowledged its involvement in the

fraud. Defendant Bristol Myers is under investigation in connection with its pricing practices for drugs covered by Medicare and Medicaid. Defendant AstraZeneca paid $355 million to settle federal fraud charges that it induced doctors to falsely bill Medicare and Medicaid. Defendant Schering-Plough has agreed to pay nearly $350 million in fines and damages, and to plead guilty to criminal charges that it defrauded Medicaid. Defendant TAP Pharmaceuticals paid $875 million in connection with its fraudulent pricing practices respecting Lupron. Defendant Warrick paid $27 million to the state of Texas to resolve allegations that it reported fraudulent price information to Medicaid. Defendant Dey paid $18 million to settle similar claims of defrauding Medicaid in Texas. *See also* Exhibit B to this Complaint (showing extent and pervasiveness of AWP spread).

14. As a result of defendants' fraudulent and illegal manipulation of Medicaid drug prices, defendants have reaped billions of dollars in illegal profits. By this action, the City of New York seeks (1) recovery of the excessive Medicaid pharmacy costs paid as a result of defendants' intentional misconduct; (2) payment of the full amount of rebates owed; (3) disgorgement of defendants' unlawful profits; (4) punitive damages; and (5) entry of an order directing defendants henceforth to report accurate wholesale price and Best Price and AMP data and pay correct rebates in compliance with federal and state statutes.

II. JURISDICTION AND VENUE

15. Plaintiff claims violations of, *inter alia*, the Social Security Act, 42 U.S.C. § 1396 *et seq*, N.Y. Social Services Law §§ 145-b and 367a, and N.Y. General Business Law § 349, and breach of contract, unjust enrichment, and common law fraud.

16. This court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, because the action alleges violations the Social Security Act, 42 U.S.C. § 1396 *et seq*.

This Court has supplemental jurisdiction over the City's state law claims pursuant to 28 U.S.C. § 1367.

17. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and (c) because defendants do business and are qualified to do business in this district; certain acts giving rise to the claims asserted in this complaint occurred within this district; and the illegal actions of defendants, as alleged in this complaint, caused damage to plaintiff within this district.

III. PARTIES

18. Plaintiff, the City of New York, is a municipal corporation organized pursuant to the laws of the State of New York. By statute, the City pays 25% of Medicaid prescription drug costs. N.Y. Soc. Serv. L. §§ 367-a and 368-a.

19. Defendants are manufacturers and sellers of prescription drugs. Each defendant conducts extensive business in the State of New York, including in New York City. Each defendant manufactures, markets and sells prescription drugs with false and inflated wholesale prices that are paid for by Medicaid in New York City.

20. Defendant Abbott Laboratories, Inc. ("Abbott") is an Illinois corporation engaged in the business of manufacturing and selling pharmaceuticals. Abbott's principal place of business is located at 100 Abbott Park Road, Abbott Park, IL. Abbott Pharmaceuticals ("Abbott Pharm") is the pharmaceutical division of Abbott.

21. Defendant Alcon Laboratories, Inc. ("Alcon") is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Alcon's principal place of business is located at 6201 S. Freeway (T1-3), Fort Worth, TX, 76115.

22. Defendant Allergan, Inc. ("Allergan") is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Allergan's principal place of business is located at 2525 Dupont Drive, Irvine, CA 92612.

23. The following two defendants are hereinafter referred to as the Alpharma Group:

(a) Defendant Alpharma, Inc. ("Alpharma") is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Alpharma's principal place of business is located at One Executive Drive, Fort Lee, NJ 07024.

(b) Defendant Purepac Pharmaceutical Co. ("Purepac"), a wholly owned subsidiary of Alpharma, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Purepac was acquired by Alpharma in December 2001. According to the SEC, Purepac's principal place of business is located at One Executive Drive, Fort Lee, NJ 07024.

24. The following two defendants are hereinafter referred to as the Amgen Group:

(a) Defendant Amgen, Inc. ("Amgen") is a Delaware corporation in the business of manufacturing and selling pharmaceuticals. Amgen's principal place of business is located at One Amgen Drive, Thousand Oaks, CA 91320-1799.

(b) Defendant Immunex Corporation ("Immunex"), a wholly owned subsidiary of Amgen since July 2002, is a Washington State corporation engaged in the business of manufacturing and selling pharmaceuticals. Immunex's principal place of business is located at 51 University Street, Seattle, WA 98101.

25. Defendant Andrx Corporation ("Andrx") is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Andrx's principal place of business is located at 4955 Orange Drive, Davie, FL 33314.

26. Defendant AstraZeneca Pharmaceuticals L.P. ("Astrazeneca") is a Delaware limited partnership engaged in the business of manufacturing and selling pharmaceuticals. AstraZeneca's principal place of business is located at 1800 Concord Pike, Wilmington, DE 19850-5437.

27. The following two defendants are hereinafter referred to as the Aventis Group:

(a) Defendant Aventis Pharmaceuticals Inc. ("Aventis Pharm") is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Aventis Pharm's principal place of business is located at 300-400 Somerset Corporate Boulevard, Bridgewater, NJ 08807-2854.

(b) Defendant Dermik Laboratories, Inc. ("Dermik"), a wholly owned subsidiary of Aventis Pharm, is a Pennsylvania corporation engaged in the business of manufacturing and selling pharmaceuticals. Dermik's principal place of business is located at 1050 Westlakes Drive, Berwyn, PA 19312.

28. Defendant Barr Laboratories, Inc. ("Barr") is a New York corporation engaged in the business of manufacturing and selling pharmaceuticals. Barr's principal place of business is located at 2 Quaker Road, P.O. Box 2900 Pomona, NY 10970-0519.

29. Defendant Bayer Corporation ("Bayer") is an Indiana corporation engaged in the business of manufacturing and selling pharmaceuticals. Bayer itself is a wholly

owned United States subsidiary of a German corporation, Bayer AG. Bayer's principal place of business is located at 100 Bayer Road, Crafton, PA 15205-9741. Bayer's Pharmaceutical subsidiary ("Bayer Pharm") is located at 400 Morgan Lane, West Haven, Connecticut.

30. Defendant Biovail Pharmaceuticals, Inc. ("Biovail") is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Biovail is a wholly owned subsidiary of Biovail Corporation, a Canadian corporation whose principal offices are located at 7150 Mississauga Road, Mississauga, Ontario, Canada, L5N 8M5. Biovail's principal place of business is located at 700 Route 202/206 North Bridgewater, NJ 08807.

31. The following four defendants are hereinafter referred to as the Boehringer Group:

(a) Defendant Boehringer Ingelheim Corporation ("Boehringer") is a Nevada corporation engaged in the business of manufacturing and selling pharmaceuticals. Boehringer's principal place of business is located at 900 Ridgebury Rd., Ridgefield, CT 06877.

(b) Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer Pharm"), a wholly owned subsidiary of Boehringer, is a Connecticut corporation engaged in the business of manufacturing and selling pharmaceuticals. Boehringer Pharm's principal place of business is located at 900 Ridgebury Rd., Ridgefield, CT 06877.

(c) Defendant Roxane Laboratories, Inc. ("Roxane"), a wholly owned subsidiary of Boehringer, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Roxane's principal place of business is located at 1809 Wilson Rd., Columbus, OH 43216-6532.

(d) Defendant Ben Venue Laboratories, Inc. ("Ben Venue"), a wholly owned subsidiary of Boehringer, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Ben Venue's principal place of business is located at 300 Northfield Road, Bedford, OH 44146.

32. The following two defendants are hereinafter referred to as the BMS Group:

(a) Defendant Bristol-Myers Squibb Company ("Bristol-Myers") is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Bristol-Myers' principal place of business is located at 345 Park Avenue, New York, NY 10154-0037. Westwood-Squibb ("Westwood") is a division of BMS.

(b) Defendant Oncology Therapeutics Network Corp. ("OTN"), a wholly owned subsidiary of Bristol-Myers, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. OTN's principal place of business is located at 395 Oyster Point Boulevard, Suite 405, South San Francisco, CA 94080.

33. Defendant Dey Inc. ("Dey"), formerly Dey Laboratories, a/k/a Dey, L.P., is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Dey is an indirect subsidiary of Merck KGaA, a German pharmaceutical conglomerate. Dey's principal place of business is located at 2751 Napa Valley Corporate Drive, Napa, CA 94558.

34. Defendant Eisai Inc. ("Eisai") is a Delaware corporation. It is a U.S. pharmaceutical subsidiary of Tokyo-based Eisai Co., Ltd. Eisai's principal place of business is located at 500 Frank W. Burr Boulevard, Teaneck, NJ 07666.

35. Defendant Eli Lilly and Company ("Eli Lilly") is an Indiana corporation engaged in the business of manufacturing and selling pharmaceuticals. Eli Lilly's principal place of business is located at Lilly Corporate Center, Indianapolis, IN 46285. Eli Lilly conducts extensive business in the State of New York, including in New York City. Eli Lilly manufactures and sells prescription drugs with false and inflated wholesale prices that are paid for by Medicaid in New York City. Dista is a division of Eli Lilly.

36. Defendant Endo Pharmaceuticals Inc. ("Endo"), a subsidiary of Endo Pharmaceuticals Holdings Inc., is a Delaware corporation. Endo's principal place of business is located at 100 Painters Drive, Chadds Ford, PA 19317.

37. Ethex Corporation ("Ethex"), a wholly owned subsidiary of KV Pharmaceutical Company ("KV"), is a Delaware corporation with its principal place of business at 10888 Metro Court, St. Louis, MO. KV is also a Delaware corporation with its principal place of business at 2503 South Hanley Road, St. Louis, MO. Ethex is in the business of manufacturing, marketing and selling prescription pharmaceuticals.

38. The following two defendants are hereinafter referred to as the Forest Group:

(a) Defendant Forest Laboratories, Inc. ("Forest") is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Forest's principal place of business is located at 909 Third Ave, New York, NY 10022.

(b) Defendant Forest Pharmaceuticals, Inc. ("Forest Pharm") is a corporation engaged in the business of manufacturing and selling pharmaceuticals. Forest Pharm is headquartered in St. Louis, Missouri and is a wholly owned subsidiary of Forest Laboratories,

Inc. Forest Pharm's principal place of business is located at 13600 Shoreline Drive, St. Louis, MO 63045.

39. The following two defendants are hereinafter referred to as the Fujisawa Group:

(a) Defendant Fujisawa Healthcare, Inc. ("Fujisawa") is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Fujisawa's principal place of business is located at Three Parkway North, Deerfield, IL 60015.

(b) Defendant Fujisawa USA, Inc. ("Fujisawa USA") was a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Fujisawa USA's principal place of business was located at Three Parkway North, Deerfield, IL 60015.

40. Defendant Genzyme Corporation ("Genzyme") is a Massachusetts corporation engaged in the business of manufacturing and selling pharmaceuticals. Genzyme's principal place of business is located at 500 Kendall Street, Cambridge, MA 02142.

41. Defendant Gilead Sciences, Inc., ("Gilead") is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Gilead's principal place of business is located at 333 Lakeside Drive, Foster City, CA, 94404.

42. The following two defendants are hereinafter referred to as the GSK Group:

(a) Defendant GlaxoSmithKline P.L.C. ("GSK"), created through the merger of Glaxo Wellcome, P.L.C. and SmithKlineBeecham P.L.C., is a British corporation engaged in the business of manufacturing and selling pharmaceuticals. GSK's principal place of business is located at 980 Great West Road, Brentford, Middlesex, EN, TW8 9, U.K. Cerenex Pharmaceuticals ("Cerenex") is a division of GSK

(b) Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("SmithKline"), a wholly owned subsidiary of the former SmithKlineBeecham P.L.C., is a Pennsylvania corporation engaged in the business of manufacturing and selling pharmaceuticals. SmithKline's principal place of business is located at One Franklin Plaza, 16th and Race Streets, Philadelphia, PA 19102.

43. The following two defendants are hereinafter referred to as the Ivax Group:

(a) Defendant Ivax Corporation ("Ivax") is a Florida (formerly Delaware) corporation engaged in the business of manufacturing and selling pharmaceuticals. Ivax's principal place of business is located at 4400 Biscayne Blvd., Miami, FL, 33137.

(b) Defendant Ivax Pharmaceuticals Inc. ("Ivax Pharm"), a wholly owned subsidiary of Ivax, is a Florida corporation engaged in the business of manufacturing and selling pharmaceuticals. Ivax Pharm's principal place of business is located at 4400 Biscayne Blvd., Miami, FL, 33137.

44. The following five defendants are hereinafter referred to as the Johnson & Johnson Group:

(a) Defendant Johnson & Johnson ("J&J") is a New Jersey corporation engaged in the business of manufacturing and selling pharmaceuticals. J&J's principal place of business is located at One Johnson & Johnson Plaza, New Brunswick, NJ, 08933.

(b) Defendant Janssen Pharmaceutical Products, LP ("Janssen"), a wholly owned subsidiary of J&J, is a New Jersey limited partnership engaged in the business of manufacturing and selling pharmaceuticals. Janssen's principal place of business is located at 1125 Trenton-Harbourton Road, Titusville, NJ 08560.

(c) Defendant Ortho-McNeil Pharmaceutical, Inc. ("Ortho McNeil"), a wholly owned subsidiary of J&J, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Ortho McNeil's principal place of business is located at 1000 U.S. Route 202 South, Raritan, NJ 08869.

(d) Defendant Ortho Biotech Products, LP ("Ortho Biotech"), a wholly owned subsidiary of J&J, is a New Jersey limited partnership engaged in the business of manufacturing and selling pharmaceuticals. Ortho Biotech's principal place of business is located at 700 U.S. Highway 202, Raritan, NJ 08869.

(e) Defendant McNeil-PPC, Inc. ("McNeil"), a wholly owned subsidiary of J&J, is a New Jersey corporation engaged in the business of manufacturing and selling pharmaceuticals. McNeil's principal place of business is located at 7050 Camp Hill Road, Fort Washington, PA 19034.McNeil Consumer & Specialty Pharmaceuticals ("McNeil Cons") is a division of McNeil.

45. The following two defendants are hereinafter referred to as the King Group:

(a) Defendant King Pharmaceuticals, Inc. ("King") is a Tennessee corporation in the business of manufacturing and selling pharmaceuticals. King's principal place of business is located at 501 Fifth St., Bristol, TN 37620.

(b) Defendant Monarch Pharmaceuticals, Inc. ("Monarch"), a wholly owned subsidiary of King is a Tennessee corporation in the business of manufacturing and selling pharmaceuticals. Monarch's principal place of business is located at 501 Fifth Street, Bristol, TN 37620. Monarch's Altace® is marketed by Monarch and by Wyeth (another defendant herein) pursuant to the Co-Promotion Agreement entered into in June 2000.

46. Defendant MedImmune, Inc. ("MedImmune") is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. MedImmune's principal place of business is located at One Medimmune Way, Gaithersburg, MD 20878.

47. Defendant Merck & Co., Inc. ("Merck") is a New Jersey corporation engaged in the business of manufacturing and selling pharmaceuticals. Merck's principal place of business is located at One Merck Drive, P.O. Box 100, Whitehouse Station, NJ 08889-0100.

48. The following three defendants are hereinafter referred to as the Mylan Group:

(a) Defendant Mylan Laboratories, Inc. ("Mylan") is a Pennsylvania corporation engaged in the business of manufacturing and selling pharmaceuticals, mainly through its subsidiaries. Mylan's principal place of business is located at 1500 Corporate Drive, Suite 400, Canonsburg, PA 15317.

(b) Defendant Mylan Pharmaceuticals, Inc. ("Mylan Pharm"), a wholly owned subsidiary of Mylan, is a West Virginia corporation engaged in the business of manufacturing and selling pharmaceuticals. Mylan Pharm's principal place of business is located at 1500 Corporate Drive, Suite 400, Canonsburg, PA 15317.

(c) Defendant UDL Laboratories, Inc. ("UDL"), a wholly owned subsidiary of Mylan, is an Illinois corporation engaged in the business of manufacturing and selling pharmaceuticals. UDL's principal place of business is located at 1500 Corporate Drive, Suite 400, Canonsburg, PA 15317.

49. The following two defendants are hereinafter referred to as the Novartis Group:

(a) Defendant Novartis Pharmaceuticals Corporation ("Novartis") is a New Jersey corporation engaged in the business of manufacturing and selling pharmaceuticals. Novartis' principal place of business is located at One Health Plaza, East Hanover, NJ 07936.

(b) Defendant Sandoz, Inc. ("Sandoz"), formerly known as Geneva Pharmaceuticals, Inc., is a wholly owned subsidiary of Novartis. Sandoz is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Sandoz's principal place of business is located at 506 Carnegie Center, Suite 400 Princeton, NJ 08540.

50. Defendant Novo Nordisk Pharmaceuticals, Inc. ("Nordisk") is a corporation engaged in the business of manufacturing and selling pharmaceuticals. Nordisk is the U.S. health care affiliate of Novo Nordisk A/S, the world's largest producer of pharmaceuticals for endocrine disorders. Nordisk's principal place of business is located at 100 College Road West, Princeton, NJ 08540.

51. Defendant Organon Pharmaceuticals USA, Inc. ("Organon") is a Delaware corporation, a subsidiary of Akzo Nobel, NV and is engaged in the business of manufacturing and selling pharmaceuticals. Organon's principal place of business is located at 56 Livingston Ave, Roseland, NJ 07068.

52. Defendant Par Pharmaceutical, Inc. ("Par") is a New Hampshire corporation engaged in the business of manufacturing and selling pharmaceuticals. Par's principal place of business is located at One Ram Ridge Road, Spring Valley, NY 10977.

53. Defendant Purdue Pharma, L.P. ("Purdue") is a pharmaceutical company engaged in the business of manufacturing and selling pharmaceuticals. Purdue's principal place of business is One Stamford Forum, 201 Tresser Boulevard, Stamford, CT.

54. Defendant Reliant Pharmaceuticals, LLC ("Reliant") is a Pennsylvania corporation engaged in the business of manufacturing and selling pharmaceuticals. Reliant's corporate headquarters is located at 110 Allen Road, Liberty Corner, NJ 07938.

55. Defendant Sanofi-Synthelabo, Inc. ("Sanofi") is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Sanofi's principal place of business is located at 90 Park Avenue, New York, NY 10016.

56. The following two defendants are hereinafter referred to as the Hoffman-LaRoche Group:

(a) Defendant Hoffman-La Roche, Inc. ("Hoffman-LaRoche") is a New Jersey corporation. Hoffman-LaRoche is the U.S. prescription drug unit of the Roche Group and is engaged in the business of manufacturing and selling pharmaceuticals. Roche's principal place of business is located at 340 Kingsland Street, Nutley, NJ 07110-1199.

(b) Defendant Roche Laboratories, Inc. ("Roche Labs"), a wholly owned subsidiary of Roche, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Roche Labs' principal place of business is located at 340 Kingsland Street, Nutley, NJ 07110-1199.

57. The following two defendants are hereinafter referred to as the Schering Group:

(a) Defendant Schering-Plough Corp. ("Schering") is a New Jersey corporation engaged in the business of manufacturing and selling pharmaceuticals. Schering's principal place of business is located at 2000 Galloping Hill Rd., Kenilworth, NJ 07033. Key Pharmaceutical ("Key") is a division of Schering. Schering Corporation ("Schering Corp") is a subsidiary of Schering

(b) Defendant Warrick Pharmaceuticals Corporation ("Warrick"), a wholly owned subsidiary of Schering, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Warrick's principal place of business is located at 12125 Moya Boulevard, Reno, NV 89506.

58. Defendant Serono, Inc. ("Serono") is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Serono's principal place of business is located at One Technology Place, Rockland, MA 02370.

59. Defendant Takeda Pharmaceuticals North America, Inc. ("Takeda") is a corporation engaged in the business of manufacturing and selling pharmaceuticals. Takeda's principal place of business is located at 475 Half Day Road, Suite 500, Lincolnshire, IL 60069.

60. Defendant TAP Pharmaceutical Products, Inc. ("TAP"), a joint venture between defendant Abbott and Takeda Chemical Industries, Ltd., of Osaka, Japan, is a corporation engaged in the business of manufacturing and selling pharmaceuticals. TAP's principal place of business is located at 675 North Field Drive, Lake Forest, IL 60045.

61. Defendant Teva Pharmaceutical Industries, Ltd. ("Teva") is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Teva's principal place of business is located at 650 Cathill Road, Sellersville, PA, 18960.

62. The following two defendants are hereinafter referred to as the Watson Group:

(a) Defendant Watson Pharmaceuticals, Inc. ("Watson") is a Nevada corporation engaged in the business of manufacturing and selling pharmaceuticals. Watson's principal place of business is located at 311 Bonnie Circle, Corona, CA 92880.

(b) Defendant Watson Pharma, Inc., formerly known as Schein ("Watson Pharma"), a wholly owned subsidiary of Watson since 2000, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Watson Pharma's principal place of business is located at 311 Bonnie Circle, Corona, CA 92880.

63. Defendant Wyeth, formerly American Home Products Corp., is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Wyeth's principal place of business is located at Five Giralda Farms, Madison, NJ 07940.Wyeth-Ayerst is a division of Wyeth.

IV. ALLEGATIONS APPLICABLE TO ALL DEFENDANTS

A. THE MEDICAID STATUTORY SCHEME

64. Medicaid was established by Title XIX of the Federal Social Security Act (the "Act"), 42 U.S.C. §§ 1396 et seq. (the "Medicaid Program"). The Act mandates the establishment of minimum health and safety standards that must be met by providers and suppliers, such as defendants, participating in the Medicaid Program.

65. State participation in Medicaid is voluntary, but once a state agrees to participate, as New York has (*see* N.Y. Social Services Law § 363 *et seq.*) the state must comply with all federal statutory requirements. The Medicaid plan proposed by each state must be approved by the federal government. *See* 42 U.S.C. § 1396a(a) and (b). New York

State's Medicaid plan has been expressly approved by the federal government. 42 C.F.R. § 433.32,at 79-29, 42 C.F.R. § 433.33, at 80-84.

66. New York State's Medicaid plan requires that local social service districts, such as the City, pay one half of the district's costs for drugs covered by Medicaid, after first deducting the federal share. N.Y. Social Services Law § 368-a. The federal share is generally 50 percent of the cost, 42 U.S.C. § 1396(d)(b), leaving the remaining 50 percent to be split equally between the State and the City.

1. Initial Medicaid Payments for Drugs Are Based on AWP

67. State law provides that Medicaid will pay providers for defendants' drugs that are "self administered," *i.e.*, dispensed at a pharmacy, based on AWPs for such drugs. N.Y. Soc. Serv. L. §367-a(9). Each prescription drug is assigned a National Drug Code ("NDC codes"), also known as a formulary code. A separate AWP is published for each drug for which there is an NDC code. The United States Food and Drug Administration publishes such codes for each of the various dosages and packagings of each drug. Prescription drugs fall into one of two general categories: brand name/patented or multi-source/generic. There are approximately 65,000 different drug products in the United States market, including different dosages and packagings of the same drug.

68. Medicaid is not alone in reimbursing based on AWP. It is standard practice for federal Medicare and Medicaid Programs and other public and private third-party payors and individuals to pay for prescription drugs based upon the AWPs for such drugs.

69. AWP serves as a benchmark for payment whether a drug is single source, (*i.e.*, exclusive or patented), or multi-source or generic (*i.e.*, a drug produced by numerous manufacturers). For multi-source or generic drugs that have at least three suppliers, the Center for Medicare and Medicaid Services generally establishes federal upper limits

("FULs") on which Medicaid reimbursement is based. The FUL is defined as 150% of the lowest reported AWP. 42 C.F.R. § 447.332. Thus, even multi-source or generic drugs for which a FUL has been set are reimbursed based on AWP.

70. AWPs are published and reported by non-party publishing services in printed and electronic compendia such as the Thomson's *RedBook* (the *RedBook*), the American Druggist First Databank Annual Directory of Pharmaceuticals, and Essential Directory of Pharmaceuticals (the *Blue Book*), and Medi-Span's Master Drug Database. These publishers report AWP based directly on wholesale price information provided by defendants. Defendants report to the publishers either an actual AWP for their drugs or other wholesale pricing information, *e.g.*, wholesale list prices, wholesale acquisition costs ("WACs"), or direct prices, which the publishers then convert to the reported AWP. In all cases, the AWP is established solely based on information provided by the drug manufacturer.

71. Specifically, N.Y. Social Services Law § 367-a(9)(b) provides for reimbursement as follows for drugs covered by Medicaid and dispensed by pharmacies:

> (i) if the drug is a multiple source prescription drug for which an upper limit has been set by the federal health care financing administration [now the Centers for Medicare & Medicaid Services], an amount equal to the specific upper limit set by such federal agency for the multiple source prescription drug, and
>
> (ii) if the drug dispensed is a multiple source prescription drug or a brand-name prescription drug for which no specific upper limit has been set by such federal agency, the lower of the estimated acquisition cost of such drug to pharmacies, or the dispensing pharmacy's usual and customary price charged to the general public. Estimated acquisition cost means the *average wholesale price* of a prescription drug based upon the package size dispensed from, as reported by the prescription drug pricing service used by the department, less twelve percent thereof, and updated monthly by the department.

N.Y. Soc.Serv.L. § 367-a(9)(b) (emphasis added).

72. Subsection (i) of this provision sets Medicaid reimbursement for multi-source drugs, including most generic drugs, at the FUL where a FUL has been established. N.Y. Soc. Serv. L. § 367-a(9)(b)(i).

73. Subsection (ii) of this provision sets Medicaid reimbursement for brand-name drugs or drugs for which no FUL has been set at the "estimated acquisition cost," which the statute defines as AWP minus 12 percent. The alternative measure of reimbursement, the "usual and customary price charged to the general public," is not used because the necessary data are not available.[1]

74. Prior to May 15, 2003, Medicaid reimbursement in New York state for brand-name drugs or drugs for which no FUL has been set was AWP minus 10 percent. The formula was amended to AWP minus 12 percent in 2003. N.Y Laws 2003, Ch. 62, Part Z2. The pricing and reimbursement data set forth in this Complaint reflect the City's 2002 Medicaid Pharmacy costs, based on the then-applicable formula for Medicaid reimbursement of AWP minus 10 percent.

75. The federal government has emphasized the importance of accurate AWPs. In its April 2003 report, Compliance Program Guidance for Pharmaceutical Manufacturers, the Office of the Inspector General of the Department of Health and Human Services ("HHS OIG") reaffirmed that the "government sets reimbursement with the expectation that the data provided are complete and accurate." The OIG made clear that the AWP must be a meaningful figure that is not artificially inflated:

> Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free

[1] In addition, the statute provides for a small dispensing fee, between $3.50 to $4.50, to be added to all reimbursements.

> goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues). Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements.

76. The OIG rejected the notion that purposeful AWP manipulation was a lawful practice:

> The "spread" is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the "spread," it controls its customer's profit.
>
> Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at "95 percent of average wholesale price." 42 U.S.C. 1395u(o). **Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP.** Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.
>
> If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike bona fide discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. **In other words, it is illegal for a manufacturer knowingly to establish or inappropriately**

> **maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product.**
>
> In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing practices. **The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute.** Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product.

[Emphases added.]

2. Medicaid Rebates Are Based on Best Price, AMP and the CPI

77. The second component of the price that Medicaid pays for prescription drugs is determined by the federally mandated rebate statute. Under the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8, a manufacturer of a drug that wishes to have its products paid for by Medicaid must enter into a rebate agreement with the Secretary of Health and Human Services. The statute requires each manufacturer of single source and brand name innovator drugs to report to Medicaid its Best Price and its AMP and to pay rebates to state Medicaid programs based on its own accurate determination of Best Price and AMP. 42 U.S.C. § 1396r-8(b)(1)(A)[2] The statute requires each manufacturer of multi-source or generic drugs to report to Medicaid its AMP and to pay rebates to state Medicaid programs based on its own accurate determination of AMP. *Id.*

[2] The federal share of any rebate amounts received by the state must be offset against the state's Medicaid expenditures that quarter for the purposes of calculating the federal financial participation. 42 U.S.C. § 1396r-8(b)(1)(B).

78. Congress passed the rebate statute expressly to help reduce state Medicaid drug expenditures. H.R. Rep. No. 101-881 at 96-8 (1990), U.S.C.C.A.N. 1990, 2017, 2108-2110.

79. New York Statute Law § 367-a(7)(d) expressly incorporates the rebate requirements of 42 U.S.C. § 1396r-8 and provides that where a manufacturer has entered into a rebate agreement, as outlined above, reimbursement to the New York State Medicaid program shall be made only pursuant to the terms of that rebate agreement.

80. New York Social Service Law also requires that the State return to the local social service district, such as New York City, the local district's *pro rata* share of any rebate received. New York's Medicaid plan was approved expressly by the federal government, so that the City is an intended third-party beneficiary of the Medicaid rebate agreements.

81. The Medicaid Rebate statute defines Best Price as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, non-profit entity or governmental entity in the United States," with certain enumerated exceptions. 42 U.S.C. § 1396r-8(c)(1)(C)(i).

82. The Medicaid Rebate Statute provides precise specifications concerning how the Best Price is to be calculated. After excluding the prices given to certain drug purchasers from the definition and including others explicitly, the Statute states:

> the term "Best Price" –
>
> (I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);
>
> (II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package; and

(III) shall not take into account prices that are merely nominal in amount.

42 U.S.C. § 1396r-8(c)(1)(C)(ii).

83. AMP, or Average Manufacturer's Price, is defined as the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts. 42 U.S.C. § 1396r-8(k)(1).

84. The rebate for brand-name drugs (defined as "single source drugs" or "innovator multiple source drugs") is the difference between the AMP and the Best Price, or 15% of the AMP, whichever is greater. 42 U.S.C. §§ 1396r-8(c)(1) – (2); N.Y. Soc. Serv. L. § 367 (a)(7)(d). The rebate for other drugs is 11.1% of AMP. 42 U.S.C. § 1396r-8(c)(3); N.Y. Soc. Serv. L. § 367 (a)(7)(d).

85. Where the cost of a drug has outpaced the increase in the consumer price index over a period of time, the Medicaid rebate statute, 42 U.S.C. § 1396r-8(c)(2), requires each drug manufacturer to pay an additional rebate. 42 U.S.C. § 1396r-8(c)(2),

86. To effectuate the purpose of the statute, manufacturers are required to report their Best Prices and AMPs to the Secretary of HHS, who is required to keep the information confidential. 42 U.S.C. §§ 1396r-8(b)(3)(A), (D).

87. The states are required to report to the manufacturers, as well as to HHS, the "information on the total number of units of each dosage strength and package size of each covered outpatient drug . . . for which payment was made under the plan during the period." 42 U.S.C. § 1396r-8(b)(2).

88. The Secretary calculates the rebates according to the statutory formulas and reports to each state a Unit Rebate Amount, which is "the amount calculated by

the Health Care Financing Administration to which the Medicaid utilization information may be applied by states in invoicing the Manufacturer for the rebate payment due." The rebate then is paid to the state Medicaid program by the defendant drug manufacturer.

89. States thus are provided with Unit Rebate Amounts, not the AMPs or Best Prices. *See* Brief of the United States as *Amicus Curiae* filed in *In re: Pharmaceutical Industry Average Wholesale Price Litigation* (No. 01-CV-12257-PBS) (MDL No. 1456 D. Mass.) at 15 (addressing, *inter alia*, that 42 U.S.C. § 1396r-8 does not preempt state law fraud claims based on fraudulent reporting of rebate data) (hereinafter "*Amicus* brief"). Like HHS, the States are also required to keep confidential the rebate-related information that they receive. 42 U.S.C. § 1396r-8(b)(3)(D).

90. While the Secretary provides supplemental guidance to manufacturers regarding their Best Price obligations through program releases and training guides, the Secretary relies entirely on the manufacturers for Best Price and AMP data.

91. The Model Rebate Agreements follow the statute in expressly providing that the manufacturers have ultimate responsibility for the calculation of the rebate:

> A State may, at its option, compute the total rebate anticipated, based on its own records, *but it shall remain the responsibility of the labeler* to correctly calculate the rebate amount based on its correct determination of AMP and, where applicable, Best Price.

Model Rebate Agreement at I(n); www.cms.hhs.gov/medicaid/drugs/drebate

92. Under the Medicaid rebate statute, any manufacturer that knowingly provides false information "is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information." "[S]uch civil money penalties *are in addition to other penalties as may be prescribed by law*." 42 U.S.C. § 1396r-8(c)(ii) (emphasis added).

93. In his *Amicus* brief, at 8, the Secretary of HHS wrote:

> States obviously have a direct and compelling interest in accurate Best Price reporting and the rebate program, which helps to reduce the costs the states themselves incurred for drugs purchased by Medicaid patients. It is within their [the state's] statutory authority to investigate and prosecute Medicaid best price violations as alleged in this case.

Because the City, like the State, is a Medicaid payor, it also has a direct and compelling interest in accurate Best Price and AMP reporting.

B. DEFENDANTS' FRAUDULENT CONDUCT

1. Intentionally False and Inflated AWPs

94. At all times relevant hereto, each defendant has intentionally reported, or caused to be reported, to industry publications wholesale pricing information that it knew to be false and inflated, with the intention and knowledge that the published information would be relied upon by Medicaid, Medicare and private payors for calculating drug payments and reimbursements.

95. This is confirmed by investigations by Congress, the General Accounting Office ("GAO") and the HHS OIG, and by litigations by the Department of Justice ("DOJ"), various state Attorneys General and U.S. Attorneys, as detailed below.

96. These reported prices were far in excess of the amounts that the manufacturers charged to wholesalers or providers, indeed higher than any purchase price paid by any participant in the drug distribution chain. In fact, AWPs are completely fictitious prices that no one ever actually pays. In some cases they are created out of thin air for the sole purpose of creating a marketable spread as described herein.

97. Even when they do not create their AWPs out of thin air, defendants report wholesale price information that they know does not take into account routine discounts, rebates, free samples and other inducements offered to providers to increase demand for their

products. For example, defendants regularly pay "chargebacks" that are not accounted for in their reported AWPs. Chargebacks are payments by defendants to drug wholesalers to compensate the wholesaler for its sales of defendants' drugs to an indirect purchaser to whom the manufacturer has agreed to sell its drugs at a deep discount.

98. Defendants also routinely pay two percent prompt pay discounts to wholesalers that are not accounted for in their reported AWPs. Prompt pay discounts are given when the purchaser pays the drug manufacturer within a prescribed period of time. Wholesalers uniformly avail themselves of prompt pay discounts. Other credits, rebates, hidden discounts and financial incentives likewise are routinely provided and not included in the AWPs or other wholesale pricing data reported by defendants.

99. Defendants know that AWPs are inflated, yet nevertheless report or cause the AWPs to be issued. Defendants at all times relevant could report accurate average wholesale prices based on good faith and reasonable estimates utilizing the pricing and transactional information defendants maintain in conducting their ordinary business affairs.

100. By increasing the spread on its drugs, each defendant seeks to influence drug-selecting entities such as physicians, pharmacies, PBMs and/or others in the drug distribution chain to increase their purchases of its drugs. Defendants engage in this purposeful manipulation for the sole and express purpose of creating demand for their products. Manufacturers market the spread to PBMs to gain inclusion into a PBM's formulary, and to pharmacists to be the exclusive supplier of a multi-source drug. PBMs and pharmacists benefit by pocketing the difference between the reported AWP and the actual cost they pay for the drug.

101. The success of this scheme is well documented. As one example, Martha McNeill, the head of Texas' Medicaid drug program, testified that when Texas cut Warrick's inhaler reimbursement from $16.79 to $6.26, Warrick's Medicaid market share for the inhaler dropped from 71% to 42% in less than 2 years. Andrew Caffrey, Scott Hensley & Russell Gold, *States Go to Court in Bid to Rein in Price of Medicine,* WALL ST. J., May 21, 2002, at A1.

102. According to HHS and industry experts, the actual average prices paid by prescription drug wholesalers are on average 27% lower than average retail prices. Yet the AWPs reported by defendants are routinely and significantly higher than they should be per that ratio. Exhibit B to this Complaint sets forth the reported AWP for certain of defendants' drugs and the amount of overcharge to the City based on an estimate of the true average wholesale price for each drug, assuming that price to be the retail price minus 27 percent. These calculations show that the AWPs as reported are on average 20 percent above true average wholesale prices. This confirms the findings of numerous governmental investigations, studies and settlements described below. Thus, even a 10 or 12 percent discount off AWP, as New York's Medicaid law mandates for brand-name drugs, results in an average overpayment of at least 8 or 10 percent.

103. In many instances, the price inflation and the corresponding overpayments are far higher. The drugs listed in Exhibit B are primarily brand name drugs. Congressional and other federal investigations have concluded that defendants' reporting of intentionally false and inflated AWPs is substantially greater in the generic or multi-source drug arena. This is hardly surprising, because competition among manufacturers – and therefore, the fight for market share – is greatest in this arena.

104. In its complaint concerning certain of the same defendants and underlying fraud, the Montana Attorney General cites an industry consultant on this point as follows:

> This situation is more pronounced with generic drugs. Many generic companies have taken advantage of this use of AWP by substantially inflating their published AWPs. . . .[T]he system allows a retailer to acquire a drug at a low cost, $2.50 per 100 tablets, for example, while relying on a published AWP ($20.00 or more) for its own pricing. It is not uncommon that the $25.00 retail price for a generic drug renders a gross profit well above $20.00 for the retailer. It is also common for the AWP of a generic product to remain stable while the actual selling price declines .... It is obvious that AWP is not an accurate measure of the prices manufacturers charge. It must also be noted that not all generic products will be priced similarly. Some, in fact, use the more traditional method of a 20% markup to reach an AWP. This can be a handicap for generic companies choosing this method because retailers often use the AWP as the starting point for many pricing decisions and an artificially high AWP provides the retailer with greater profits.

105. Generic or multi-source drug manufacturers are aware of the AWPs reported by their competitors and of the actual sales price of their generic competitors' products. Generic drug manufacturers manipulate their own AWPs in order to gain or maintain a competitive advantage in the market for their generic products. The effect is what has been called a "leap frogging" where all AWPs for a particular generic spiral upwards as companies attempt to create spread.

106. The natural and expected result is that multi-source drugs have some of the highest spreads of any drugs, sometimes resulting in an AWP exceeding actual costs by over 50,000%. A few examples collected by the DOJ are set forth below:

Defendant	Multi-source Drug	*RedBook* AWP	DOJ Determined Actual AWP	Percentage Spread
Baxter	Dextrose	$ 928.51	$ 2.25	41,167%
Baxter	Sodium Chloride	$ 928.51	$ 1.71	54,199%

Defendant	Multi-source Drug	*RedBook* AWP	DOJ Determined Actual AWP	Percentage Spread
Boehringer*	Leucovorin Calcium	$ 184.40	$ 2.76	6,581%
B. Braun	Sodium Chloride	$ 11.33	$ 1.49	660%
Bristol-Myers Group*	Etoposide (Vepesid)	$ 136.49	$ 34.30	298%
Dey*	Albuterol Sulfate**	$ 30.25	$ 9.17	230%
Immunex*	Leucovorin Calcium	$ 137.94	$ 14.58	846%
Pharmacia	Etoposide	$ 157.65	$ 9.47	1,565%
Sicor Group	Tobramycin Sulfate	$ 342.19	$ 6.98	4,802%
Watson*	Vancomycin HCL	$ 70.00	$ 3.84	1,567%

* Defendants herein.
**Drugs Herein

107. Whether they manufacture brand name drugs or generics, all defendants engage in the deceptive wholesale price reporting described herein to create demand for their products.

2. The Role of PBMs in the AWP Scheme

108. PBMs specialize in the administration and management of prescription benefit programs. Their clients include HMOs, employers, preferred provider organizations and other health insurers. Three PBMs, AdvancePCS/Caremark, Express Scripts and Medco Health, together control eighty percent of the PBM market and supply the prescription drugs of approximately 210 million people in the United States. *See* David A. Balto, *Competitive Concerns and Price Transparency in the PBM Market*, UPDATE, September/October 2003, at 35.

109. PBMs operate in two primary businesses: First, PBMs contract with pharmaceutical manufacturers, retail pharmacies, and health plans to decide which drugs should be included in formularies, to bill health plans for prescription drug payments on behalf

of plan participants, and to pay the pharmacies. Second, PBMs operate their own proprietary mail order pharmacies.

110. PBMs' historic business model was to procure drugs for their health plan client in exchange for administrative fees. According to the Wall Street Journal, "[t]raditionally, PBMs received only modest administrative fees for arranging prescriptions at cost." Barbara Martinez, *Rx for Margins: Hired to Cut Costs, Firms Find Profits Inn Generic Drugs, Pharmacy-Benefit Managers Can Take Huge Markups And Still Offer 'Discounts,' Making $170 on just 90 Pills*, WSJ., March 31, 2003, at A1.

111. This model has changed in recent years such that PBMs now are "increasingly . . . reducing those fees and trying to take advantage of the "spread" between pharmacy prices and what corporate and government clients pay. Express Scripts say most of its contracts now include spread pricing." *Id.*

112. The following is an example of a typical PBM transaction and a description of the contracts that underpin it. A health plan participant is prescribed a drug by a physician. The participant fills the prescription at a PBM-approved pharmacist, paying only the co-pay. The pharmacist buys the drug either directly from the manufacturer or from a wholesaler. The pharmacist then bills the PBM for the drugs it sells to the patient. The PBM has a contract with the retail pharmacy to pay a price at a certain discount off AWP, e.g., AWP minus 15%. The PBM in turn bills the health plan for this drug. However, the PBM has a separate contract with the health plan, entitling it to payment at a different, higher rate, e.g., AWP minus 10%. Thus, in addition to any administrative fee the PBM receives, the PBM receives the spread between the contractual payment it receives from the health plan and the contractual payment it makes to the pharmacist. Furthermore, if the PBM operates its own

mail-order pharmacy that health plan members are required to use, the PBM reaps the pharmacist's share of the spread as well.

113. In the Introduction to this Complaint, plaintiff set forth an example of how PBMs and pharmacists profit from the spread in the case of Fluoxetine.

114. PBMs select their formularies based on the profits they can make, including the spread between actual price and AWP, and taking into account rebates, discounts, chargebacks and other incentives that the manufacturers provide:

> PBMs develop relationships with manufacturers that provide lower pricing (through rebates) when a particular drug is on the formulary.... In general, the level of rebates increases if the PBM increases a greater market share for a drug within a defined class of prescriptions with similar therapeutic effects.

Providing Prescription Drug Coverage Through Medicare: The Role of Pharmacy Benefit Managers, U.S. Senate Committee on Finance (Mar. 29, 2000), at 4-5 found at http://www.senate.gov/~finance/3-29mcca.htm.

115. Defendants know and understand that third-party payors and PBMs rely on the *RedBook* and other compendia to determine the AWPs of the covered drugs, both brand name and generic. Because defendants control the published AWPs, defendants know and understand that they can manipulate the providers' and PBMs' profits, gained at the expense of third-party payors, including the City, to incentivize these providers and PBMs to prescribe their drugs and/or to include their drugs in a drug formulary by inflating the AWPs.

116. Because the PBMs consider the contracting relationship with retail pharmacies to be confidential, health plans are never informed of the reimbursement amount to pharmacies. Nor are they informed of the actual prices that pharmacies pay for the drugs.[3]

3. Failure to Report Best Prices and Pay Proper Rebates

117. The same routine discounts, rebates, free samples and other inducements offered to providers but excluded in setting AWP are also excluded from defendants' calculations of Best Price. These include chargebacks, two percent prompt pay discounts, free samples distributed by sales representatives, and other credits, rebates, and hidden discounts and financial incentives.

118. Certain defendants also engage in re-labeling schemes to avoid reporting Best Price. Federal law expressly prohibits this practice. 42 U.S.C. § 1396r-8(c)(ii). For example, in 2003, two defendants herein, Bayer and GSK, agreed to pay $344 million to resolve allegations that they engaged in health care fraud against state programs by failing to report their "Best Price" for certain drugs. In their wrongful scheme, known as "lick and stick," they sold drugs to Kaiser Permanente Medical Care Program (the nation's largest HMO) at deep discounts, but avoided including these discounts in their Best Price calculations by re-labeling the products with new NDC codes before sale.

119. As described below, the HHS OIG has documented that such repackaging schemes are widespread. OIG, *Medicaid Drug Rebates – Sales To Repackagers Excluded From Best Price Determinations*, at 1, 4 (March 2001).

120. Upon information and belief, each of the defendant pharmaceutical companies has also utilized an array of other inducements to stimulate sales of their drugs.

[3] The FTC issued a public notice on March 26, 2004 that Congress had requested that they conduct a study into possible conflicts of interest between PBMs and the group health plans to which they provide services. *See* http://www.ftc.gov/os/2004/03/040326pnpbm.pdf.

These inducements, including educational grants, volume discounts, and rebates or free goods, were designed to result in a lower net cost to the purchaser while concealing the actual cost price beneath a high invoice price. A product invoiced at $100 for ten units of a drug might really only cost the purchaser one-half that amount. If one assumes a subsequent shipment of an additional ten units at no charge, or a "grant," "rebate" or "credit memo" in the amount of $50, the transaction would truly cost just $5 per unit net. Through all these off-invoice means, drug purchasers are provided the substantial discounts that induce their patronage while maintaining the fiction of a higher invoice price -- the price that corresponds to reported AWPs and inflated reimbursement from Medicaid.

121. As explained below, certain defendants also are under investigation for abusing the nominal price exception to Best Price reporting, created by Congress as a public policy exception to encourage drug manufacturers to continue to sell drugs at nominal prices to entities serving the public good, without the manufacturer having to pay increased rebates because of those sales. The exception allows drug companies to exclude from their Best Price calculations drugs with prices less than 10% of AMP. 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(III).

V. GOVERNMENT INVESTIGATIONS

122. DOJ, GAO, HHS OIG, and a number of Congressional and Senate committees have investigated and are continuing to investigate defendants for questionable practices regarding the reporting of wholesale pricing information, Best Price, AMP, and other non-compliance with Medicaid Rebate statute.

123. The House Committee on Energy and Commerce is conducting an investigation into pharmaceutical reimbursements and rebates under Medicaid. On June 26, 2003, Chairman Billy Tauzin (R-La.) and Oversight and Investigations Subcommittee

Chairman James Greenwood (R-PA) wrote as follows to 26 drug companies, including many defendants herein:[4]

> The Committee on Energy and Commerce is conducting an investigation into pharmaceutical reimbursements and rebates under Medicaid. This inquiry builds upon the earlier work by this Committee on the relationship between the drug pricing practices of certain pharmaceutical companies and reimbursement rates under the Medicare program. In that investigation, the Committee uncovered significant discrepancies between what some pharmaceutical companies charged providers for certain drugs and what Medicare then reimbursed those providers for dispensing those drugs. This price difference resulted in profit incentives for providers to use the drugs of specific companies as well as higher costs to the Medicare system and the patients it serves. For example, we learned that one manufacturer sold a chemotherapy drug to a health care provider for $7.50, when the reported price for Medicare was $740. The taxpayer therefore reimbursed the doctor almost $600 for dispensing the drug and the cancer patient had a $148 co-payment. Such practices are unacceptable in the view of the Committee, which is why we are in the process of moving legislation to address these abuses.
>
> The Committee has similar concerns regarding drug prices in Medicaid, which has a substantially larger pharmaceutical benefit than Medicare.

House Committee on Energy and Commerce, June 26, 2003 Press Release, "Tauzin, Greenwood Expand Medicaid Fraud Investigation."

124. The letter requests extensive and specific detail about the subject companies' sales, AWPs, AMPs, and WACs, and their records relating to calculation of Best Prices and their use of the nominal price exception.

[4] The targeted companies include defendants Abbott Labs; Alpharma; Aventis Pharmaceuticals; Barr Labs; Bristol Myers; Dey; Ethex; Eli Lilly; Geneva; GlaxoSmithKline; IVAX; Johnson & Johnson; Mylan Pharmaceuticals; Par Pharmaceuticals; Purepac; Roche; Roxane; Schering-Plough; TEVA; UDL Labs; Warrick Pharmaceuticals; and Watson.

125. Congressmen Tauzin and Greenwood sent comparable letters to the nation's largest pharmaceutical chains. *See* House Committee on Energy and Commerce January 19, 2004 Press Release "Tanzin, Greenwood Expand Medicaid Fraud Investigation".

126. Many of the drugs under Congressional scrutiny, including Albuterol, Buspirone, Fluoxetine, Buspar, Celebrex, and Zyprexa, are drugs for which New York City's Medicaid spends large sums. *See* Exhibit A.

127. On April 29, 2004, in the latest bipartisan effort to rein in Medicaid costs, the Senate Finance Committee sent letters to 19 drug companies[5] focusing on whether those companies exploited the nominal price exception. The Committee wrote:

> We understand that some drug manufacturers may be using the Nominal Price Exception as part of their commercial pricing practices. These practices could undermine the purposes of the Medicaid Best Price policy and may be costing taxpayers hundreds of millions of dollars through reduced Medicaid rebates.

Senate Finance Committee Press Release dated April 29, 2004, "Grassley, Baucus Ask Drug Manufacturers Question About How They Price Drugs For Medicaid."

128. The House and Senate Medicaid investigations described above follow comparable investigations regarding Medicare in 2000 – 2001. Congressman Pete Stark (D-Ca.) chaired that investigation.

129. In a letter dated September 28, 2000, Congressman Stark wrote to the president of the Pharmaceutical Research and Manufacturers of America ("PhRMA"), of which most of the Defendants are members, as follows:

[5] Target companies include defendants GlaxoSmithKline, Johnson & Johnson, Merck & Co., Inc., AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Company, Novartis Pharmaceuticals Corporation, Amgen, Inc., Wyeth Pharmaceuticals, Eli Lilly & Company, Aventis Pharmaceuticals, Inc., Abbott Laboratories, Hoffman-La Roche Inc., TAP Pharmaceutical Products Inc., Schering-Plough Corporation, Boehringer Ingelheim Pharmaceuticals, Inc., Forest Pharmaceuticals, Inc., Sanofi-Synthelabo and Eisai, Inc.

> Drug company deception costs federal and state governments, private insurers and others billions of dollars per year in excessive drug costs. This corruptive scheme is perverting the financial integrity of the Medicare program and harming beneficiaries who are required to pay 20% of Medicare's current limited drug benefit. Furthermore, these deceptive, unlawful practices have a devastating financial impact upon the states' Medicare Program. . . .
>
> The evidence I have obtained indicates that at least some of your members have knowingly and deliberately falsely inflated their representations of the average wholesale price ("AWP"), wholesaler acquisition cost ("WAC") and direct price ("DP") which are utilized by the Medicare and Medicaid programs in establishing drug reimbursements to providers. The evidence clearly establishes and exposes the drug manufacturers themselves that were the direct and sometimes indirect sources of the fraudulent misrepresentation of prices. Moreover, this unscrupulous "cartel" of companies has gone to extreme lengths to "mask" their drugs' true prices and their fraudulent conduct from federal and state authorities. I have learned that the difference between the falsely inflated representations of AWP and WAC versus the true prices providers are paying is regularly referred to in your industry as "the spread." . . .
>
> The evidence is overwhelming that this "spread" did not occur accidentally but is the product of conscious and fully informed business decisions by certain PhRMA members. . . .

September 28, 2000 letter from House Committee on Ways and Means, Subcommittee on Health, to Alan F. Holmer, President, Pharmaceutical Research and Manufacturers of America, Washington, D.C. Congressional Record, Extension of Remarks at E1622.

130. Congressman Stark came to the following five "shocking conclusions":

> First – Certain drug manufacturers have abused their position of privilege in the United States by reporting falsely inflated drug prices in order to create a de facto improper kickback for their customers.
>
> Second – Certain drug manufacturers have routinely acted with impunity in arranging improper financial inducements for their physicians and other healthcare provider customers.

> Third – Certain drug manufacturers engage in the fraudulent price manipulation for the express purpose of causing federally funded health care programs to expend scarce tax dollars in order to arrange de facto kickbacks for the drug manufacturers' customers at a cost of billions of dollars.
>
> Fourth – Certain drug manufacturers arrange kickbacks to improperly influence physicians' medical decisions and judgments notwithstanding the severely destructive effect upon the physician/patient relationship and the exercise of independent medical judgment.
>
> Fifth – Certain drug manufacturers engage in illegal price manipulation in order to increase utilization of their drugs beyond that which is necessary and appropriate based on the exercise of independent medical judgment not affected by improper financial incentives.

Id. E1623-24

131. In a letter to Abbott dated October 31, 2000, Congressman Stark wrote:

> You should by now be aware of Congressional investigations revealing that [your company] has for many years reported and published inflated and misleading data and has engaged in other deceptive business practices. This letter is a call for your company to immediately cease overcharging taxpayers and jeopardizing public health . . . .
>
> The price manipulation scheme is executed through [your company's] inflated representations of average wholesale price (AWP) and direct price ("DP") which are utilized by the Medicare and Medicaid Programs in establishing drug reimbursements to providers. The difference between the inflated representations of AWP and DP versus the true price providers are paying, is regularly referred to in your industry as "the spread." The evidence amassed by Congress clearly shows that [your company] has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that [your company] manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs. This was achieved by arranging financial benefits or inducements that